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| 09/574,519      | 05/18/2000  | Eric Henderson       | 7164.01             | 8198             |

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| EXAMINER |
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FREDMAN, JEFFREY NORMAN

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1637

DATE MAILED: 03/20/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/574,519**

Applicant(s)  
**Henderson et al**

Examiner  
**Jeffrey Fredman**

Art Unit  
**1637**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 5, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56-63 and 65-92 is/are pending in the application.
- 4a) Of the above, claim(s) 86-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-63, 65-85, and 89-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 17
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Newly submitted claims 86-88 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The system is drawn to a device for synthesizing an array and not to the molecular array itself. This would be separately classified in Class 422, subclass 50 and is distinct because it differs in structure and properties from the array itself.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 86-88 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 112***

2. In view of the removal of the rejected subject matter, the rejection of claims 56-63 and 67-75 under 35 U.S.C. 112, first paragraph, is withdrawn.

3. Claims 91 and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 appears to fail to further limit claim 91 because it recites substrates other than mica, while claim 91 is limited to mica. Therefore, it is indefinite if the substrate, which claim 91

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requires to have a domain for binding of the molecule is composed of mica or is composed of mica with a layer of some other substance such as glass.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 56-63, 65, 67, 68, 75-78 and 81 are rejected under 35 U.S.C. 102(a) as being anticipated by Dontha et al (J. Pharm. Biomed. Analysis (February 1999) 19:83-91).

Dontha teaches a molecular array for characterizing molecular interaction events comprising a) a surface (page 85, columns 1 and 2) and b) at least one molecular deposition domain deposited on said surface wherein the spatial address of the domain is less than one micron in area. Dontha expressly states "Sub-micron sized domains of a carbon surface are derivatized with antibodies using biotin/avidin technology (abstract)" (also see page 85, columns 1 and 2 and abstract). In figure 2, Dontha shows deposition domains which comprise spots, irregular shapes, some shapes which appear more linear and deposition of products at known locations. Dontha teaches that 10 microliters of photobiotin is used on a surface of 1 square mm diameter at a concentration of 10 mg/ml (page 85, column 1), and since photobiotin has a MW of 593.7, the solution of 10 microliters contains approximately  $1 \times 10^{17}$  molecules of photobiotin. This number, divided by the number of square microns per square mm which is 1,000,000,

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demonstrates that there are approximately  $1 \times 10^{11}$  molecules of photobiotin spread over each micron, which is more than two molecules per deposition domain. This also meets the high density limitation and the array is inherently modified by a carboxyl group upon addition of the photobiotin. Dontha further teaches the express deposition of a protein and antibody onto the array which proteins inherently have the property of being either hydrophobic or hydrophilic (see figure 1, page 86).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 56-63, 65-85 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dontha in view of Eggers et al (U.S. Patent 5,532,128) and further in view of Brenner (U.S. Patent 5,604,097).

Dontha teaches the limitations of claims 56-63, 65, 67, 68 and 75 as discussed above. Dontha expressly indicates the method is of use for biomolecules (page 84, column 2). Dontha also expressly suggests patterning on Silicon surfaces (of which glass is a member) (page 87, column 1) as well as gold surfaces (page 87, column 1). Dontha does not teach the particular equivalents, DNA, RNA, silanes or alkanethiolates.

Eggers teaches the placement of DNA, RNA, oligonucleotides thereof, antibodies, antigens and silanes onto solid supports (column 7, line 60 to column 8, line 15).

Brenner teaches the placement of alkanethiolates onto solid supports (column 12, line 45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the Dontha array with the use of other molecules as taught by Eggers and Brenner since Dontha expressly motivates the use of other biomolecules (page 84, column 2) and since Eggers demonstrates the equivalence of these items, stating "Different probes can be attached to the test sites 14 according to the type of target desired, including the use of oligonucleotides, single or double stranded DNA or RNA, antibodies or antigen-antibody complexes, tumor cells and other test probes known to those of skill in the art (column 7, lines 61-66)". As MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency

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must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982).” Here, Eggers and Brenner demonstrate the equivalency in the prior art.

8. Claims 56-63, 65-85 and 89-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dontha in view of Eggers et al (U.S. Patent 5,532,128) and further in view of Brenner (U.S. Patent 5,604,097) and further in view of Seeman et al (U.S. Patent 6,255,469).

Dontha in view of Eggers and further in view of Brenner teach the limitations of claims 56-63, 65-85 and 89-90 as discussed above. Dontha in view of Eggers and further in view of Brenner do not teach the use of mica substrates.

Seeman teaches the use of mica substrates for DNA assays.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the Dontha in view of Eggers and further in view of Brenner array with the use of a mica support since Seeman teaches “

“Annealing a hairpin to a crystalline array by hydrogen bonding can occur in solution or after deposition on a mica surface. Thus, from a small set of starting DX crystal components, it is possible to produce a diversity of ordered DNA arrays each displaying different surface features.” Thus, an ordinary practitioner would have been motivated to use mica because mica can be used to form ordered DNA arrays. Further, as MPEP 2144.06 notes “

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Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982).” Here, Seeman teaches that Mica is a known array equivalent.

### *Response to Arguments*

9. Applicant's arguments filed February 5, 2002, have been fully considered but they are not persuasive.

Applicant argues that the photopatterned lines in the Dontha reference are the domains and continues to argue that the lines are at least 50 microns in length with a total area of at least 40 microns. Applicant is reading the reference and claim differently, and more narrowly, than the examiner. Broadly read, the claim simply requires that there are two elements, first a substrate, and second a domain of less than one micron in area which includes a biological or chemical molecule. There is no dispute that Dontha teaches a substrate. The examiner reads the claim as permitting each separate submicron region to be a domain, and not to limit the domains in the claim to some larger feature. This is the reason for the calculation found in the rejection. The calculation shows that the photobiotin molecules, if evenly spread about the surface, would yield more than 2 molecules per domain. There is no requirement that the



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domains be distinguishable from one another in any way, and so the domains of Dontha necessarily and inherently incorporate submicron domains with at least two photobiotin molecules. Thus, to be absolutely clear, every submicron element on a line is considered a separate domain (this can be seen on a AFM view of the patterned element), because there is no requirement for physical separation between the domains.

As a separate point, the cited Dontha paper from Analytical Chemistry, cited in the 1449, at page 2625, figure 5, shows a series of domains within the larger image.

Applicant then separately argues the references in the prima facie obviousness rejection. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant then argues no expectation of success for detection of the domain. This argument is directly rebutted by Dontha, who successfully detects the attachment. Here again, no requirement that separate detection of different domains is present in the claims.

Applicant then argues that the new claims have a "known location" requirement. This limitation does not distinguish from Dontha, who knows the location of the deposited material but simply does not have domains which are physically separated.

The examiner notes that Applicant has not identified an element of the array which is structurally impacted by the use of a microsphere in the synthesis. Because the claim is to the

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array and not to the method of making or to the device for making, the microsphere limitation is only relevant insofar as it causes a different array to form. If some physical difference related to this element is identified by the specification, applicant is requested to identify the difference and the basis for the difference in the specification.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

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The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**Jeffrey Fredman**  
**Primary Patent Examiner**  
**Art Unit 1637**

March 14, 2002